## REMARKS

Applicants respectfully request reconsideration of the above-identified patent application in view of the following remarks. Claims 6-10 are pending.

## Finality of Rejection

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Applicants respectfully request that the finality of the rejection be withdrawn. In Amendment A, applicants did not amend the claims. That first Office Action contained a rejection of claims 6-10 under 35 U.S.C. §102 that was not repeated in this second Office Action. Moreover, the only rejection under 35 U.S.C. §103 was a rejection of claim 10 that was based upon a showing of anticipation of independent claim 6. In the present Final Office Action, there is one rejection that is presented for the first time and is not necessitated due to a claim amendment. Therefore, applicants respectfully request that the finality of the present Office Action be removed. Applicants shall address the one rejection below.

## 35 U.S.C. 103 Rejection

Claims 6-10 were rejected for the first time under 35 U.S.C. §103 as unpatentable over WO98/15645. In the previous Office Action, WO98/15645 was used to reject claims 6-9 as anticipated. Therefore, this rejection, the only rejection of the Office Action, is presented for the first time.

The Examiner has alleged that the distinction as to how the indicator dye is admixed with a polymeric material (that is different as between WO98/15645 and the present invention) "are of no patentable moment with respect to the pending device claims." Problematically, the Examiner characterized both the reference and the claimed invention as follows: "The biological indicator of WO98/15645 is used in a closed environment that is indistinguishable from the claimed method of intended use and would have been able to perform the claimed function of oxygen indication." (emphasis added) Applicants respectfully traverse this rejection because the Examiner seems to be looking at a non-elected set of claims from the prior restriction requirement.

The reiterate, the present patent application presented two sets of claims. Claims 1-5 (now canceled in view of the restriction requirement) were directed to a process for making an oxygensensitive polymeric structure. Claims 6-10 (elected and pending) are directed to a product-by-process. The Examiner made the restriction requirement final, despite applicants traversal. Therefore, the present claims are product-by-process claims.

The Examiner's assertions in the Final Office Action appear to recognize the different processes for making as between the present invention (both the elected and non-elected parts) and the single reference, WO98/15645. However, the above-quoted statement from the Final Office

Action seems to indicate that the pending claims are directed to a method for using. The present claims are a product-by-process. The product claims is for a **multi-layered component** that has at least two essential components. The two components are (1) "an indicator polymer product film" and (2) "a plurality of non-oxygen sensing polymer films bonded thereto." The process goes on to describe how to make the indicator product film. Perhaps the Examiner is getting confused by the preamble statement of "having an ability to detect oxygen presence within a packaging material?"

The Examiner concluded in this first-time presented rejection that "it would have been within the skill of the art to modify WO98/15645 and use a plurality of layers to gain the above advantages to achieve the expected result of preventing the escape of sample." That statement (1) does not describe the claimed invention, (2) nor does it provide any clue where the prior art reference (WO98/15645) discloses or even suggests how it should be modified. Moreover, that statement does not consider the technical field of the claimed invention relating to having a packaged sealed as a means for testing the integrity of the seal, and not testing for the presence of microorganisms as in WO98/15645. A prior art reference must be read in its entirety and not just a part out of context. WO98/15645 suggests forming a barrier from external contamination in order to test an internal sample (see page 12 lines 4-8). Moreover, WO98/15645 teaches away from the claimed invention by suggesting spraying an admixture of dye and polymer onto a solid support (page 12 lines 38) and that the preferred embodiment describes the solid support as a "porous material" (page 13 line 4). Having a porous material teaches away from the claimed invention that is designed to detect oxygen within a package and not the presence of oxygenconsuming microorganisms. Accordingly, modifying WO98/15645, even if suggested in WO98/15645, would not have disclosed or suggested the present invention.

Further still, the present invention is not the result of optimizing a variable. No variables were optimized to achieve the present invention. The process of the product-by-process claims is a novel process that is not taught or suggested in WO98/15645. Specifically, WO98/15645 discloses an indicator made "by admixing an oxygen sensitive dye with a polymeric material." The Examiner improperly alleges that the dye "is used in a closed package environment indistinguishable from the claimed method": The invention of claims 6-10 is a product-by-process invention as the process claims were restricted out as a separately patentable invention.

With regard to the process, WO98/15645 discloses a solvent-based approach to making oxygen-sensing devices. The WO98/15645 process provides that the dye is dissolved in a suitable solvent in which suitable polymers are also co-dissolved thereby creating a solution of uniformly dispersed molecules of the two components. This effectively yields a paintable, sprayable or castable solution that leaves a coating of polymer mixed with dispersed dye molecules after the solvent is evaporated. WO98/15645 teaches away from the present process of claims 1-5 because the inventive process does not use a solvent approach. Instead, the inventive process of claims 1-5

describes an alternative approach of directly dissolving the dye into polymer based on melting the polymer. Therefore, WO98/15645 teaches away from the inventive process of claims 1-5, claims that were found by the Examiner to be patentably distinct from product-by-process claims 6-10.

Moreover, WO98/15645 is not analogous art because it addresses a different problem. Therefore, the present invention of either claims 6-10 pending or claims 1-5 restricted out is not "a mere duplication of parts" as the Examiner alleged. Further, further allegations by the Examiner of "optimization of a result" are not supported nor are they even relevant because there is no suggestion in WO98/15645 to such alleged "optimization." Lastly, the arrival at a conclusion of obviousness seems to be based upon hindsight gleaned from the present invention as such suggestions do not appear to be found in any of WO98/15645. Accordingly, withdrawal of this sole remaining rejection is respectfully requested.

Applicants respectfully request withdrawal of the remaining newly-presented rejection and allowance of pending claims 6-10.

Respectfully submitted,

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